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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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26753	7590	07/05/2006	EXAMINER	
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202			REIDEL, JESSICA L	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,950

Applicant(s)

XUE ET AL.

Examiner

Jessica L. Reidel

Art Unit

3766

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 9, 2006 has been entered.

2. Acknowledgement is made of Applicant's Amendment, which was received by the Office on June 9, 2006. Claims 2 and 20 have been cancelled. Claims 1 and 3-19 are pending. The new title: "Method of Analyzing Non-Invasive Cardiac Parameters", has been accepted.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the step of "measuring a 3-D QRS-T angle, wherein the measuring of the 3-D QRS-T angle is effectuated with an area detection method" must be shown or the feature(s) canceled from the claim(s). In addition, the "measured 3-D QRS-T angle" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

Art Unit: 3766

even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: although there is support in the specification for the measuring a QRS-T angle (either two dimensional or three dimensional) preferably by calculating the angular difference between a QRS vector and a T vector, there is not support found in the disclosure for the steps of “measuring a 3-D QRS-T angle, wherein the measuring of the 3-D QRS-T angle is effectuated with an area detection method”.

Claim Objections

5. Claim 1 is objected to because of the following informalities: the language and format of the claim is awkward. The Examiner suggests revising the claim as follows:

A method of using an electrocardiogram signal, the method comprising:

assessing a patient's cardiac vulnerability to sudden cardiac death by:

determining a first value representative of a 3-D QRS-T angle for a first beat of the electrocardiogram signal;

determining a second value representative of a 3-D QRS-T angle for a second beat of the electrocardiogram signal;

wherein the first and second value representations are determined using an area detection method; and

determining variation of the first value and the second value.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 3-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although there is support in the specification for the measuring a QRS-T angle (either two dimensional or three dimensional) preferably by calculating the angular difference between a QRS vector and a T vector, there is not support found in the disclosure for the steps of

Art Unit: 3766

“measuring a 3-D QRS-T angle, wherein the measuring of the 3-D QRS-T angle is effectuated with an area detection method”. This limitation of an “area detection method” is new matter.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1 and 3-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what an “area detection method” employs, how the method is used to measure a 3-D QRS-T angle and what exact steps and/or system components are actually involved.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claim 1 recites the limitation “determining variation between the first value and the second value”, which appears to be an abstract idea rather than a practical application of that idea. The Examiner suggests adding a tangible, useful and concrete method step wherein the method “employs” the “determining” by “performing an action” or “completing a method step”. To explain further and/or clarify, the Examiner notes that a physician/clinician has the ability to “determine a variation between the first value and the second value” using his mind. This is abstract and lacks utility. The Examiner further makes reference to Claim 18 where a similar

Art Unit: 3766

limitation is recited that *has* utility: “analyzing variation of the first value and the second value using a time series analysis” [emphasis added]. The Examiner suggests incorporating a similar type of limitation in Claim 1 (see dependant Claim 9 for example) to overcome this rejection and add utility to the claim. The Examiner points out, however, that if a limitation is added to Claim 1 to overcome this rejection that is identical to what is already present in Claim 18, both claims will be objected under 37 CFR 1.75 as being a substantial duplicate thereof.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. In view of the Drawing and Specification Objections above, and further in view of the 35 U.S.C. 112, first and second paragraph rejections above, the following rejections are based on prior art which can be applied to the claims as to the best understanding of the Examiner.

14. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson (U.S. 4,136,690). Anderson discloses a method using an electrocardiogram (ECG) signal comprising measuring a QRS-T angle, read as defining a relationship, between the QRS peak vector, read as depolarization, and the T-wave peak vector, read as repolarization. Anderson discloses that the QRS-T angle is “successively stored” and the Examiner interprets this to mean that the QRS-T angle is determined for a first beat of the ECG, a second beat of the ECG and successive beats of the

Art Unit: 3766

ECG (see Anderson column 2, lines 19-50 and column 3, lines 8-64). Anderson further discloses that each stored QRS-T angle is tallied into one of a number of angular ranges for analysis and comparison between ranges (see Anderson column 3, lines 57-67, column 7, lines 43-47 and column 8, lines 59-66). It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Anderson, the accumulated data stored, displayed or printed and used for analysis in the method of Anderson assesses a patient's cardiac vulnerability to sudden cardiac death because any arrhythmias present in the vectorcardiograph can be detected and classified and arrhythmias are a well known precursor to sudden cardiac death. The Examiner takes the position that a method, which classifies arrhythmias present in a patient's ECG signal, inherently assesses "vulnerability" to "sudden cardiac death" since an arrhythmia present in a patient's ECG indicates that a patient is more "vulnerable" to experiencing "sudden cardiac death". Anderson further discloses that the method (as discussed above), may be employed by measuring a 3-D QRS-T angle measured using an area detection method or loop measuring method commonly associated with a 3-D vectorcardiograph (see Anderson column 1, lines 12-67, column 2, lines 1-16 and column 3) using a three-lead system such as the Frank lead system or the modified McFee lead system (see Anderson column 1, lines 11-33).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson. Anderson discloses the claimed invention except the method does not specify selecting the first beat and the second beat from median beats or mean beats. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson to include selecting the first beat and the second beat from median or mean beats since it was known in the art that such a statistical selection method is used to provide means for lessening the affect that spurious signals have on the diagnosis results.

17. Claims 4-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Burnes (U.S. 2004/0220635). As to Claims 4 and 5, Anderson discloses the claimed invention as discussed above except that it is not specified that the method include defining the relationship between depolarization and repolarization to include a QRS duration and a T/QT duration.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Burnes, the detection of increased dispersion disclosed is capable of assessing a patient's

Art Unit: 3766

cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. In addition the detection of increased dispersion disclosed by Burnes is inherently indicative of an increased “vulnerability” to “sudden cardiac death”. Burnes further discloses that determination of the dispersion of the ARI includes QRS duration and QT duration and QRS duration and T duration (see Burnes page 1, paragraphs 3-5 and page 6, paragraphs 53-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Burnes to include defining the relationship between depolarization and repolarization to further include QRS duration and T/QT duration in order to provide indication of a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death.

18. As to Claim 8, Anderson discloses the claimed invention as discussed above except that it is not specified that the first beat be within a first range of heart rate and the second beat be within a second range of heart rate that is different from the first.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed

by Burnes, the detection of increased dispersion disclosed is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. In addition the detection of increased dispersion disclosed by Burnes is inherently indicative of an increased "vulnerability" to "sudden cardiac death". Burnes further discloses that dispersion measurements may be performed on a periodic basis for monitoring heart failure status, monitoring arrhythmia risk, or optimizing a therapy in order to reduce dispersion, for example by adjusting cardiac pacing parameters during CRT or adjusting the dosage of a drug therapy (see Burnes page 5, paragraph 47). It is inherent the such an optimization would include selecting a first beat from an ECG signal obtained from the patient prior to the event and selecting the second beat from an ECG signal obtained from the patient after the event. It is also inherent that a first beat selected in this manner would be from an ECG having a heart rate within a first range and a second beat selected in this manner would be from an ECG having a heart rate within a second range that is different from the first due to the administered therapy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Burnes to include a step of selecting the first beat from an ECG obtained from the patient prior to an event and selecting the second beat from an ECG obtained from the patient after the event where the event includes administering a pharmaceutical drug to a patient in order optimize the invention.

19. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kaplan et al. (U.S. 4,732,157) (herein Kaplan). Anderson discloses the

claimed invention as discussed above except that the method does not further comprise conduction a time series analysis of the first and second values.

Kaplan, however, teaches that is known to use a time series to quantify beat-to-beat variability in an ECG waveform in order to determine susceptibility to ventricular fibrillation (see Kaplan column 5, lines 12-23 and column 6, lines 1-22). Kaplan also discloses that an objective of the time series analysis on a plurality of beats is to derive a numerical parameter from the ECG, which is associated with susceptibility to ventricular fibrillation (see Kaplan Abstract and column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kaplan to include a time series analysis in order to derive a numerical parameter associated with susceptibility to ventricular fibrillation.

20. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Verrier et al. (U.S. 5,265,617) (herein Verrier '617). Anderson discloses the claimed invention as discussed above except that the method does not further comprise using a cardiac parameter or heart rate variability in addition to the ECG signal to assess the patient's cardiac vulnerability to sudden cardiac death.

Verrier '617, however, discloses a method and apparatus for the non-invasive diagnosing of cardiac vulnerability to ventricular fibrillation that comprises evaluating heart rate variability in addition to T-wave alternans of the ECG signal (see Verrier '617 Title and Abstract). Verrier '617 discloses that heart rate variability is a measure of autonomic influence, which is a major factor in triggering cardiac arrhythmias and that by simultaneous analysis of the ECG signal and heart rate variability allows for the extent and cause of cardiac vulnerability to be assessed so

Art Unit: 3766

that drug therapy may be tailored per patient (see Verrier '617 column 4, lines 54-67 and column 5, lines 1-5). The Examiner takes the position that heart rate variability is synonymous with a cardiac parameter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Verrier '617 to include simultaneous evaluation of heart rate variability in addition to the ECG signal to better assess the patient's vulnerability to sudden cardiac death and to tailor a drug therapy as best to treat the patient.

21. Claims 12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Ralph et al "Blunted arterial baroreflex causes 'pathological' heart rate turbulence", cited by Applicant (herein Ralph). Anderson discloses the claimed invention as discussed above except that the method does not further comprise using heart rate turbulence in addition to the EC signal.

Ralph, however, teaches that it is known to utilize a characteristic of baroreflex function such as heart rate turbulence (either onset or slope) as set forth in the Abstract and the third paragraph on page 2, as a superior predictor of sudden cardiac death. In particular, Ralph discloses that turbulence onset is defined prior to a premature ventricular contraction and after the premature ventricular contraction and turbulence slope is defined within the first 20 sinus-rhythm intervals after the premature contraction. The Examiner takes the position that PVCs naturally have varying cycle lengths and varying morphologies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson, to include heart rate turbulence in addition to analysis of the ECG signal as

Art Unit: 3766

taught by Ralph, since such a modification would provide a substantial improvement in the ability to predict sudden cardiac death.

22. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Ralph and Verrier et al. (U.S. 5,560,370) (herein Verrier '370). The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not comprise using data corresponding to blood pressure change in addition to heart rate turbulence to assess the patient's cardiac vulnerability to sudden cardiac death.

Verrier '370, however, discloses a method for prediction of cardiac electrical instability that uses baroreflex sensitivity as an additional indicator of cardiac electrical instability and that this sensitivity may be non-invasively characterized as blood pressure (see Verrier '370 column 20, lines 34-45). It would have been obvious to one having ordinary skill in the art to modify the method of Anderson in view of Ralph and Verrier to include using data corresponding to blood pressure in addition to heart rate turbulence to non-invasively assess the patient's cardiac vulnerability to sudden cardiac death.

23. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Ralph and Burnes. The previously modified Anderson reference discloses the claimed invention except that selecting the first beat from an electrocardiogram signal obtained from the patient is not disclosed to occur prior to an event and selecting the second beat from an electrocardiogram signal obtained from the patient is not disclosed to occur at least one of during and after the event where the event includes at least one of administering a pharmaceutical drug to a patient, pacing the patient using exercise, and pacing the patient using an implanted pacemaker.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. In addition the detection of increased dispersion disclosed by Burnes is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. Burnes also discloses that dispersion measurements may be performed on a periodic basis for monitoring heart failure status, monitoring arrhythmia risk, or optimizing a therapy in order to reduce dispersion, for example by adjusting cardiac pacing parameters during CRT or adjusting the dosage of a drug therapy (see Burnes page 5, paragraph 47). It is inherent the such an optimization would include selecting a first beat from an ECG signal obtained from the patient prior to the event and selecting the second beat from an ECG signal obtained from the patient after the event. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Ralph and Burnes to include a step of selecting the first beat from an ECG obtained from the patient prior to an event and selecting the second beat from an ECG obtained from the patient after the event where the event includes administering a pharmaceutical drug to a patient in order optimize the invention.

Art Unit: 3766

24. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kaplan and Verrier '617. The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise using a cardiac parameter or heart rate variability in addition to the ECG signal to assess the patient's cardiac vulnerability to sudden cardiac death.

Verrier '617, however, discloses a method and apparatus for the non-invasive diagnosing of cardiac vulnerability to ventricular fibrillation that comprises evaluating heart rate variability in addition to T-wave alternans of the ECG signal (see Verrier '617 Title and Abstract). Verrier '617 discloses that heart rate variability is a measure of autonomic influence, which is a major factor in triggering cardiac arrhythmias and that by simultaneous analysis of the ECG signal and heart rate variability allows for the extent and cause of cardiac vulnerability to be assessed so that drug therapy may be tailored per patient (see Verrier '617 column 4, lines 54-67 and column 5, lines 1-5). The Examiner takes the position that heart rate variability is synonymous with a cardiac parameter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kaplan and Verrier '617 to include simultaneous evaluation of heart rate variability in addition to the ECG signal to better assess the patient's vulnerability to sudden cardiac death and to tailor a drug therapy as best to treat the patient.

Response to Arguments

25. Applicant's arguments, see page 9 of the Remarks filed June 9, 2006, with respect to Claim 1 and the Burnes reference have been fully considered and are persuasive. The 35 U.S.C. 102(e) rejection of April 7, 2006 has been withdrawn.

26. Applicant's arguments, see page 8 of the Remarks filed June 9, 2006, with respect to Claim 1 and the Anderson reference have been fully considered but they are not persuasive. Anderson discloses that the method (as discussed above), may be employed by measuring a 3-D QRS-T angle measured using an area detection method or loop measuring method commonly associated with a 3-D vectorcardiograph (see Anderson column 1, lines 12-67, column 2, lines 1-16 and column 3) using a three-lead system such as the Frank lead system or the modified McFee lead system (see Anderson column 1, lines 11-33). As mentioned above in this Action, the rejections are based on prior art which can be applied to the claims as to the best understanding of the Examiner due to the Drawing and Specification Objections, and further in view of the 35 U.S.C. 112, first and second paragraph rejections (see above).

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ferek-Petric (U.S. 6,760,615) teaches the benefits of employing vectorcardiograph techniques versus traditional one-dimensional techniques in order to study electrical characteristics of the heart.


Ferek-Petric (U.S. 6,766,190) also teaches the benefits of employing vectorcardiograph techniques versus traditional one-dimensional techniques in order to study electrical characteristics of the heart.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jessica L. Reidel 06/26/06
Examiner
Art Unit 3766


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766